FORM PTO-1390 (REV. 11-2000) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: 23660-00623

U.S. APPLICATION NO (If known, see 37 CFR 1.5): 09/936202

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US00/03871	04 February 2000 (04.02.00)	05 February 1999 (05.02.99)

TITLE OF INVENTION: **SURGICAL GUIDE LINE ASSEMBLY AND SEPARATOR FOR USE DURING A SURGICAL PROCEDURE**

APPLICANT(S) FOR DO/EO/US: **EVA Corporation**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below
4. [ ] The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   - a [ ] is attached hereto (required only if not communicated by the International Bureau)
   - b [X] has been communicated by the International Bureau
   - c [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [ ] An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))
   - a [ ] is attached hereto
   - b [ ] has been previously submitted under 35 U.S.C. 154(d)(4)
7. [ ] Amendments to the claims of the International Aplication under PCT Article 19 (35 U.S.C. 371(c)(3))
   - a [ ] are attached hereto (required only if not communicated by the International Bureau)
   - b [ ] have been communicated by the International Bureau.
   - c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   - d [ ] have not been made and will not be made
8. [ ] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3))
9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4))
10. [ ] An English lanugage translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5))

Items 11 to 20 below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98
12. [X] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [ ] A FIRST preliminary amendment
14. [ ] A SECOND or SUBSEQUENT preliminary amendment
15. [ ] A substitute specification
16. [ ] A change of power of attorney and/or address letter
17. [ ] A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825
18. [ ] A second copy of the published international application under 35 U.S.C. 154(d)(4)
19. [ ] A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4)
20. [X] Other items or information: **Copy of International Search Report**

U.S. APPLICATION NO (if known, see 37 CFR 1.5) 09/936202	INTERNATIONAL APPLICATION NO PCT/US00/03871	ATTORNEY'S DOCKET NUMBER 23660-00623

21. [X] The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):		CALCULATIONS PTO USE ONLY
Neither international preliminary examination fee (37 CFR 1 482) nor international search fee (37 CFR 1 445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO.	$1000.00	
International preliminary examination fee (37 CFR 1 482) not paid to USPTO but International Search Report prepared by the EPO or JPO	$860.00	
International preliminary examination fee (37 CFR 1 482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO	$710.00	
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)	$690.00	
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)	$100.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =		$ 690.00
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [X] 30 months from the earliest claimed priority date (37 CFR 1.492(e))		$ 130.00

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	22 - 20 =	2	x $18.00	$ 36.00
Independent claims	5 - 3 =	2	x $80.00	$160.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)	0		+ $270.00	$ 0.00
TOTAL OF ABOVE CALCULATIONS =				$ 1016.00
[X] Applicant claims small entity status. See 37 CFR 1 27 The fees indicated above are reduced by 1/2			+	$ 508.00
SUBTOTAL =				$ 508.00
Processing fee of **$130.00** for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1 492(f))				$ -0-
TOTAL NATIONAL FEE =				$
Fee for recording the enclosed assignment (37 CFR 1 21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3 28, 3.31). **$40.00** per property +				$ 40.00
TOTAL FEES ENCLOSED =				$ 548.00
			Amount to be refunded:	$
			charged:	$

a. [X] A check in the amount of $ 548.00 to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed

c. [ ] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. _____ A duplicate copy of this sheet is enclosed.

d. [ ] Fees are to be charged to a credit card. **WARNING:** Information on this form may become public **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO

SIGNATURE

JOHN N. COULBY
NAME

43,565
REGISTRATION NUMBER

SURGICAL GUIDE LINE ASSEMBLY AND SEPARATOR ASSEMBLY FOR USE DURING A SURGICAL PROCEDURE

CROSS REFERENCE TO RELATED APPLICATION

This application relates to and claims priority on U.S. Provisional Application No. 60/118,779, filed February 5, 1999, and 60/137,702, filed June 7, 1999.

FIELD OF THE INVENTION

The present invention relates generally to a surgical guide line assembly. In particular, the present invention is directed to a surgical guide line assembly for use in remote controlled surgical procedures. The present invention also related to a separator assembly for use in connection with the surgical guide line assembly to ensure that surgical components do not become entwined during a surgical procedure.

BACKGROUND OF THE INVENTION

Recent developments in the repair of abdominal aortic aneurysms permit minimally invasive surgical procedures through either an axillary or brachial incision or both. This requires the remote manipulation of both a repair graft and surgical components.

OBJECTS OF THE INVENTION

It is an object of the present invention to provide a guide line assembly for use in intravascular surgical procedures.

It is another object of the present invention to provide a guide line assembly for use in the manipulation of a surgical component within a vessel during an intravascular surgical procedure.

It is another object of the present invention to provide a guide line assembly for use in the manipulation of a repair graft assembly within a vessel during a surgical procedure for repairing an aneurysm.

It is another object of the present invention to provide a guide line assembly having a simple construction.

It is another object of the present invention to provide a guide line assembly that can be releasably secured to a surgical component for manipulation of the component within a vessel during a surgical procedure.

It is another object of the present invention to provide a guide line assembly that is capable of being attached to a surgical component at least one location.

It is another object of the present invention to provide a guide line assembly having a flexible curved end portion.

It is another object of the present invention to provide a separator assembly for use during a surgical procedure to ensure that surgical components do not become entwined during a surgical procedure.

It is another object of the present invention to provide a separator assembly that is capable of manipulating a graft assembly within a vessel.

It is another object of the present invention to provide a separator assembly having a separating assembly that is capable of rotating within the vessel.

It is another object of the present invention to provide a separator assembly having a separating assembly that is capable of being selectively locked with the vessel.

SUMMARY OF THE INVENTION

The present invention is directed to a surgical guide line assembly for use during a surgical procedure. The surgical guide line assembly permits the manipulation of a surgical component within a vessel during a surgical procedure, such as for example an intravascular procedure. The surgical guide line assembly includes a guide line component having a proximal end and a distal end, and at least one suture secured to the distal end of the guide line component. The surgical guide line assembly may further include a surgical needle connected to each of the at least one suture. The surgical guide line according to the present invention may further include a broad line assembly that is positioned around the distal end of the guide line component and a portion of the at least one suture. The broad line assembly produces a flexible curved end portion of the guide line assembly.

The surgical guide line assembly may further include a control assembly connected to the guide line component. The control assembly permits manipulation of the guide line assembly within the vessel from a remote location.

The present invention is also directed to a surgical guide line assembly for use during a surgical procedure. The surgical guide assembly permits the manipulation of a surgical component within a vessel during a surgical procedure, such as for example an intravascular procedure. The surgical guide line assembly includes a guide line component having a

proximal end and a distal end, and at least one suture secured to the distal end of the guide line component. The surgical guide line assembly may further include a surgical needle connected to each of the at least one suture. The at least one suture according to the present invention may be secured to the guide line component in one of several ways. It may be bonded directly to the component. The at least one suture may be secured to the guide line component within a formed cavity in the distal end of the guide line component. Alternatively, the suture may be secured to the distal end of the guide line component within a central passageway in the component.

In accordance with embodiments of the present invention, the guide line component may have a bent portion located adjacent the distal end. Alternatively, the guide line component may have an articulated portion located adjacent the distal end. The control assembly is capable of permitting manipulation of the articulated portion of the guide line component.

The present invention is also directed to a surgical separator assembly for use in separating at least two surgical components during a surgical procedure in a vessel. The surgical separator assembly includes a separating assembly for receiving the at least two surgical components during the surgical procedure. The surgical separator assembly further includes an advancing assembly for advancing the separating assembly within the vessel during the surgical procedure. The advancing assembly may include a catheter. The separating assembly may be rotatably connected to the advancing assembly. The separator assembly further includes a control assembly for selectively locking the separating assembly to prevent rotation of the separating assembly. In accordance with the present invention, the separating assembly may include at least two apertures therein. Each of the apertures is sized to receive at least a portion of a surgical component therein.

The present invention is also directed to a surgical system for use during a surgical procedure within a vessel. The surgical system includes both the guide line assemblies described herein in combination with the surgical separator assembly.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only, and are not restrictive of the invention, as claimed. The accompanying drawings, which are incorporated herein by reference, and which constitute a part of this specification, illustrate certain embodiments of

the invention, and together with the detailed description serve to explain the principles of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described in conjunction with the following drawing in which like reference numerals designate like elements and wherein:

Fig. 1 is a perspective view of a guide line assembly according to an embodiment of the present invention;

Fig. 2 is a schematic view of the guide line assembly according to Fig. 1 secured to a repair graft;

Fig. 3 is a schematic view of a guide line assembly according to another embodiment of the present invention secured to a repair graft;

Fig. 4 is a cross section of the guide line component of Figs. 1-3 according to one embodiment of the present invention;

Fig. 5 is a cross section of the guide line component of Figs. 1-3 according to another embodiment of the present invention;

Fig. 6 is a cross section of the guide line component of Figs. 1-3 according to another embodiment of the present invention;

Fig. 7 is a cross section of the guide line component of Figs, 1-3 according to another embodiment of the present invention;

Fig. 8 is a partial cross section of a guide line assembly according to another embodiment of the present invention;

Fig. 9 is a perspective view of the guide line assembly according to the embodiment of Fig. 8;

Fig. 10 is a perspective view of a guide line assembly according to another embodiment of the present invention;

Fig. 11 is a perspective view of the end portion of the guide line component according to an embodiment of the present invention;

Fig. 12 is a perspective view of the end portion of the guide line component according to another embodiment of the present invention;

Fig. 13 is a perspective view of the end portion of the guide line component according to another embodiment of the present invention;

Fig. 14 is a perspective view of a guide line assembly according to another embodiment of the present invention;

Fig. 15 is a perspective view of a guide line assembly according to another embodiment of the present invention;

Fig. 16 is a perspective view of a guide line and suture separating assembly according tot he present invention;

Fig. 17 is a cross section view of the head of the separating assembly of Fig. 16; and

Fig. 18 is a schematic view of the separator assembly of Fig. 16 in accordance with the present invention used to position a graft assembly within a vessel.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The above-described figures depict various surgical guide line assemblies according to embodiments of the present invention. These guide line assemblies are adapted for use in connection with the surgical repair of an aneurysms, as described in copending U.S. Patent Application No. 09/121,706, entitled "SURGICAL CUTTING DEVICE" filed on July 24, 1998, the disclosure of which is incorporated herein by reference. At least one guide line assembly may be used to align and manoeuvre a repair graft, disclosed in U.S. Patent Application Nos. 08/896,415, entitled "METHOD AND APPARATUS FOR THE SURGICAL REPAIR OF ANEURYSMS" filed on July 18, 1997, now U.S. Patent No. 5,944,750, specification of which is incorporated herein by reference, within an infra, juxta or renal positioning. The guide line assemblies may be radially positioned about the perimeter of the proximal lip of the repair graft assembly and extend caudad to the femoral incision and thereafter to a hand controller **2**, shown in Fig. 2. It is also contemplated that the guide line assemblies may extend cephalad to the axillary or brachial incision. The operation of the hand controller permits the manipulation of the at least one guide line assembly, which in turn adjusts the positioning of the repair graft assembly within the vessel during the surgical procedure.

Use of the various guide line assemblies disclosed herein according to the present invention is not limited to the repair of aneurysms. It is contemplated by the present inventors that the guide line assemblies disclosed herein according to the present invention may be used in connection with numerous intravascular procedures.

The guide line assembly **10** according to an embodiment of the present invention, depicted in Fig. 1, will now be described in greater detail. Guide line assembly **10** includes a guideline component **11**. The guide line component **11** has a distal end which is located within the vessel during the surgical procedure and a proximal end which extends from within the vessel. The guide line assembly **10** further includes at least one suture **12** connected to the guide line component **11**. The at least one suture **12** is secured to one end of the guide line component **11**. The guide line component **11** has sufficient length such that it may extend from within the vessel caudad to the femoral incision and thereafter to a hand controller **2**. The guide line component **11** is preferably formed from nitonol. It, however, is contemplated that the guide line component **11** may be formed from a similar biocompatible material.

At least one suture **12** is secured to the guide line component **11**. The embodiment of the present invention illustrated in Figs. 1 and 2 includes a pair of sutures **12**. The present invention, however, is not limited to a pair of sutures **12**. It is contemplated that a single suture **12** may be used as shown in Fig. 3. Furthermore, it is also contemplated that a plurality of sutures may extend from the distal end of the guide line component **11**. The sutures **12** are mechanically coupled to the distal end of the guide line component **11**. For example, the at least one suture **12** may be bonded to the end of the guide line component **11**, as shown for example in Fig. 1.

Other forms of coupling are considered to be well within the scope of the present invention. For example, another coupling attachment is illustrated in the embodiment depicted in Fig. 8. In this embodiment, the at least one suture **12** is crimped to the end of the guide line component **11**. A formed cavity **14** is provided in the end portion of the guide line component **11**. The at least one suture **12** is inserted into the formed cavity **14** such that the at least one suture **12** is held firmly in place upon crimping of the end of the guide line component **11**. Additionally, an insert **15** may be provided within the cavity **14**. The at least one suture **12** may be positioned around the insert **15** such that upon crimping of the end of the guide line component **11** the at least suture **12** is firmly secured to it. Fig. 9 is a perspective view of the end of the guide line component **11** in the crimped position.

Fig. 10 illustrates another embodiment of the coupling attachment for the guide line component **11**. In this embodiment, the at least one suture **12** is crimped within the hollow

portion, shown in Figs. 4-7, of the guide line component **11**. With this arrangement, no secondary drilling is required. In the embodiments illustrated in Figs. 8-10, detailing of the transition between the guide line component **11** and the at least one suture **12** may be required to remove potential burrs as well as round the corners to prevent the unintentional separation of the guide line component **11** and the at least one suture **12**. Furthermore, this detailing will prevent the guide line assembly **10** from becoming unintentionally caught within the vessel.

The guideline assembly **10** according to embodiments of the present invention includes a surgical needle assembly **13** secured to one end of the suture **12**. The provision of the surgical needle assembly **13** facilitates the attachment of the guide line assembly **10** to a repair graft assembly **1**, as shown for example in Figs. 2 and 3.

The guide line component **11** may be formed in one of several profiles, as depicted in Figs. 4-7. Fig. 4 illustrates a guide line component **11** according to the present invention having a rectangular profile **111** having rounded corners. The rounded corners facilitate smooth movement of the guide line assembly **10** within the vessel. The rectangular profile **111** may have a solid construction. A hollow or tubular construction having a central aperture **1110**, shown in phantom, is also considered to be well within the scope of the present invention.

Fig. 5 illustrates a profile for the guide line component **11** according to another embodiment of the present invention. The guide line component **11** illustrated in Fig. 5 has an elongated or obround profile **112** having rounded ends. As discussed above in connection with the rounded corners, the rounded ends facilitate smooth movement of the guide line assembly **10** within the vessel. Additionally, the elongated profile **112** may have a solid construction. A hollow or tubular construction having a central aperture **1120**, shown in phantom, is also considered to be well within the scope of the present invention.

Fig. 6 illustrates a profile for the guide line component **11** according to another embodiment of the present invention. The guide line component **11** illustrated in Fig. 6 has an elliptical profile **113**. The elongated profile **113** may have a solid construction. A hollow or tubular construction having a central aperture **1130**, shown in phantom, is also considered to be well within the scope of the present invention.

Fig. 7 illustrates a profile for the guide line component **11** according to yet another embodiment of the present invention. The guide line component **11** illustrated in Fig. 7 has a circular profile **114**. The circular profile **114** may have a solid construction. A hollow or tubular construction having a central aperture **1140**, shown in phantom, is also considered to be well within the scope of the present invention.

In accordance with embodiments of the present invention, the distal end of the guide line component **11** may have a linear orientation, as shown in Fig. 11. Alternatively, the distal end of the guide line component **11** may have a bent configuration **41**, as shown in Fig. **12**. The distal end of the guide line component **11** may be articulated to facilitate manipulation of the guide line assembly **10** within the vessel for positioning a surgical component such as for example a repair graft assembly **2**, as shown in Fig. 13. In this embodiment, the guide line component **11** includes an articulated segment **31** located adjacent the distal end. The articulated segment **31** may be manually adjusted by the surgeon. It, however, is contemplated that the articulated segment **31** may be remotely adjusted using the hand controller **2** or other suitable manipulation assembly.

The operation of the guide line assembly **10** will now be described in connection with a repair graft assembly **2**. It, however, is contemplated by the inventors of the present invention that the guide line assembly **10** may be used with other surgical components for use in other intravascular procedures. The guide line assembly **10** is secured to the repair graft assembly **2**. Specifically, the surgical needle **13** is inserted through the lip of the repair graft assembly **2**. The surgical needle **13** is then looped around the suture **12** to secure the guide line assembly **10** to the repair graft assembly **2**. The surgical needle **13** is then removed. The repair graft **2** can then be inserted and maneuvered within the vessel. The positioning of the repair graft **2** within the vessel can be adjusted using the hand controller **2**.

The guide line assembly **20** according to another embodiment of the present invention, depicted in Fig. 14, will now be described in greater detail. Guide line assembly **20** includes a guide line component **21**. The guide line component **21** is fairly stiff. The guide line component **21** has a distal end which is located within the vessel during the surgical procedure and a proximal end which extends from within the vessel. The guide line assembly **20** is manipulated within the vessel adjacent the proximal end of the guide line

component **21**. The guide line assembly **20** further includes at least one suture **22** connected to the guide line component **21**. The at least one suture **22** is secured to one end of the guide line component **21**. The guide line component **21** has sufficient length such that it may extend from within the vessel caudad to the femoral incision and thereafter to a hand controller as shown in Fig. 1 in connection with guide line assembly **10**. The guide line component **21** is preferably formed from nitonol. It, however, is contemplated that the guide line component **11** may be formed from a similar biocompatible material.

At least one suture **22** is secured to the guide line component **21**. The embodiment of the present invention illustrated in Fig. 14 includes a pair of sutures **22**. The present invention, however, is not limited to a single suture **22**. It is contemplated that more than one suture **22** may be used. The suture **22** is mechanically coupled to the distal end of the guide line component **21**. For example, the at least one suture **22** may be bonded and/or crimped to the end of the guide line component **21**. Other forms of coupling, however, are considered to be well within the scope of the present invention.

The guide line assembly **20** according to embodiments of the present invention includes a surgical needle assembly **23** secured to one end of the suture **22**. The provision of the surgical needle assembly **23** facilitates the attachment of the guide line assembly **10** to a repair graft assembly **20** or other suitable surgical component within the vessel.

The distal end of the guide line assembly **20** may be curved, as shown in Fig. 14. A broad line assembly **24** surrounds the suture **22** adjacent the distal end of the guide line component **21**. The broad line assembly **24** permits the distal end of the guide line assembly **20** to retain its curved shape. The broad line assembly **24** is preferably flexible. It is preferably formed from a spring type material. The end of the guide line component **21** and the suture **22** may be coated and/or sheathed with a thin layer **25** of Gore-Tex® or other suitable material. The thin layer **25** prevents the curved end portion of the guide line assembly **20** from snagging when it is manipulated within the vessel and/or removed from the vessel.

A guide line assembly **50** according to another embodiment of the present invention is illustrated in Fig. 15. The guide line assembly **50** includes a guide line component **51**, which is fairly stiff. The component **51** may be formed from a thin metal rod or needle. The component **51** has a distal end that is located within the vessel during the surgical procedure

and a proximal end that extends from within the vessel. The guide line assembly **50** further includes at least one suture **52** secured to the distal end of the component **51**. A surgical needle assembly **53** is secured to one end of the suture **52**. The surgical needle assembly **53** may be straight or curved, as shown in Fig. 15.

During a surgical procedure, it is possible that several guide line assemblies, described above, may be located within the vessel. It is possible that during the surgical procedure these guide line assemblies and sutures may become entwined, which may hamper the surgical procedure. Therefore, it is desirable to provide an assembly that is capable of separating any entwined guide line assemblies and sutures. A suture and guide line separator assembly **60** will now be described in connection with Figs. 16 and 17. The separator assembly **60** includes a catheter assembly **61**. One end of the catheter assembly **61** includes a separating assembly **62** connected thereto. The separating assembly **62** is capable of rotating about the axis of the catheter assembly **61**. The separating assembly **62** includes a plurality of opening **621** are sized to receive a guide line assembly or a suture therein. An opposite end of the catheter assembly **61** includes a handle assembly **63**. The handle assembly **63**, when compressed, locks the separating assembly **62** in place such that it cannot rotate about the axis of the catheter assembly **61**.

The operation of the separator assembly **60** will now be described. The free ends of the suture and guide line assemblies are threaded through the openings **621** in the separating assembly **62**. The separator assembly **60** is advanced within the vessel along the sutures and guide line assemblies. The free ends of the sutures and the guide line assemblies located outside the vessel are preferably held in place to prevent insertion into the vessel while the separator assembly **60** is advanced to its furthest most position within the vessel. While the separator assembly **60** is advanced, the separating assembly **62** freely rotates about the catheter assembly **61**. Once the separator assembly **60** reaches its furthest position within the vessel, the handle assembly **63** is operated to lock the separating assembly **62** to prevent its rotation. The separator assembly **60** may then be withdrawn from the vessel during which time the sutures and guide line assemblies may be straightened out and untangled. It is contemplated that the separator assembly **60** may be used in connection with any of the above described guide line assemblies. It is further contemplated that the separator assembly **60** may be used to separate sutures or a combination of sutures and guide line assemblies. It is

further contemplated that the separator assembly **60** may be used in connection with any other surgical component that is capable of being entangled within a vessel during a surgical procedure.

It is further contemplated that the separator assembly **60** may be used to position and rotate a graft assembly **7** within the vessel, as shown in Fig. 18. A single suture **5** may be fed through two openings **621** in the separating assembly **62** and loops **71** on the graft assembly **7**. The graft assembly **7** may be advanced into position within the vessel by inserting the separator assembly **60** into the vessel. As the separator assembly **60** is inserted, the graft assembly **7** and the separating assembly **62** will rotate freely about the axis of the catheter assembly **61**. When the graft assembly **7** reaches the desired location, the handle assembly **63** is operated to prevent rotation of separating assembly **62**. The catheter assembly **61** may then be rotated to position the graft assembly **7** in the desired location.

It will be apparent to those skilled in the arts that various modifications and variations can be made in the construction and configuration of the present invention, without departing from the scope or spirit of the invention. It is intended that the present invention cover the modifications and variations of the invention, provided they come within the scope of the appended claims and their equivalence.

WHAT IS CLAIMED IS:

1. A surgical guide line assembly for use during a surgical procedure, said surgical guide line assembly comprising:

a guide line component having a proximal end and a distal end; and

at least one suture secured to the distal end of said guide line component.

2. The surgical guide line assembly according to Claim 1, further comprising:

a control assembly connected to said guide line component, wherein said control assembly permits manipulation of said guide line assembly.

3. The surgical guide line assembly according to Claim 1, wherein each of said at least one suture includes a first end secured to said distal end of said guide line component, and a second free end, said surgical guide line assembly further comprising:

a surgical needle connected to said second end of said at least one suture.

4. The surgical guide line assembly according to Claim 1, wherein said guide line component has a bent portion located adjacent said distal end.

5. The surgical guide line assembly according to Claim 1, wherein said guide line component has an articulated portion located adjacent said distal end.

6. The surgical guide line assembly according to Claim 5, further comprising:

a control assembly connected to said guide line component, wherein said control assembly enables manipulation of said guide line assembly.

7. The surgical guide line assembly according to Claim 6, wherein said control assembly enables manipulation of said articulated portion of said guide line component.

8. The surgical guide line assembly according to Claim 1, wherein said at least one suture is secured to said guide line component within a formed cavity in said distal end of said guide line component.

9. The surgical guide line assembly according to Claim 1, wherein said guide line component has a central passageway extending therein, said at least one suture is secured to said distal end of said guide line component within said central passageway.

10. The surgical guide line assembly according to Claim 1, wherein said at least one suture is bonded to said distal end of said guide line component.

11. A surgical guide line assembly for use in a vessel during a surgical procedure, said surgical guide line assembly comprising:

a guide line component having a proximal end and a distal end;

at least one suture secured to the distal end of said guide line component;

a control assembly connected to said guide line component adjacent said proximal end, wherein said control assembly enables manipulation of said guide line assembly within the vessel; and

a surgical needle connected to said at least one suture.

12. The surgical guide line assembly according to Claim 11, wherein said guide line component has a bent portion located adjacent said distal end.

13. The surgical guide line assembly according to Claim 11, wherein said guide line component has an articulated portion located adjacent said distal end.

14. The surgical guide line assembly according to Claim 13, wherein said control assembly permits manipulation of said articulated portion of said guide line component.

15. A surgical guide line assembly for use during a surgical procedure, said surgical guide line assembly comprising:

a guide line component having a proximal end and a distal end;

at least one suture secured to the distal end of said guide line component; and

a broad line assembly positioned around said distal end of said guide line component and a portion of said at least one suture.

16. The surgical guide line assembly according to Claim 15, wherein said broad line assembly produces a flexible curved end portion of said guide line assembly.

17. The surgical guide line assembly according to Claim 15, wherein each of said at least one suture includes a first end secured to said distal end of said guide line component, and a second free end, said surgical guide line assembly further comprising:

a surgical needle connected to said second end of said at least one suture.

18. The surgical guide line assembly according to Claim 15, further comprising:

a thin layer of material positioned about said distal end of said guide line component and said at least one suture adjacent said broad line assembly.

19. The surgical guide line assembly according to Claim 18, wherein said thin layer of material is formed from Gore-Tex®.

20. A surgical separator assembly for use in separating at least two surgical components during a surgical procedure in a vessel, said surgical separator assembly comprising:

separating means for receiving the at least two surgical components during the surgical procedure;

advancing means for advancing said separating means within the vessel during the surgical procedure, wherein said separating means is rotatably connected to said advancing means; and

control means for selectively locking said separating means to prevent rotation of said separating means about said advancing means.

21. The surgical separator assembly according to Claim 20, wherein said separating means includes at least two apertures therein, wherein each of said at least two apertures is sized to receive at least a portion of the surgical component therein.

22. A surgical system for use during a surgical procedure within a vessel, said surgical system comprising:

at least two surgical guide line assemblies for use during the surgical procedure, wherein each of said surgical guide line assemblies comprising a guide line component having a proximal end and a distal end, and at least one suture secured to the distal end of said guide line component; and

a surgical separator assembly for use in separating said at least two surgical guide line assemblies during the surgical procedure, wherein said surgical separator assembly comprising separating means for receiving the at least two surgical components during the surgical procedure, advancing means for advancing said separating means within the vessel during the surgical procedure, wherein said separating means is rotatably connected to said advancing means, and control means for selectively locking said separating means to prevent rotation of said separating means about said advancing means.

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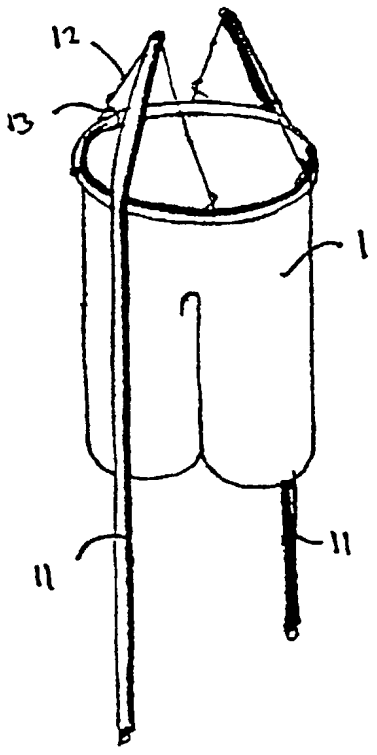
(54) Title: SURGICAL GUIDE LINE ASSEMBLY AND SEPARATOR ASSEMBLY FOR USE DURING A SURGICAL PROCEDURE

(57) Abstract

The present invention is directed to a surgical guide line assembly (10) for use during a surgical procedure. The surgical guide assembly (10) permits the manipulation of a surgical component with a vessel during a surgical procedure, such as for example an intravascular procedure. The surgical guide line assembly (10) includes a guide line component (11) having a proximal end and a distal end, and at least one suture (12) secured to the distal end of the guide line component (11). The present invention is also directed to a surgical separator assembly (60) for use in separating at least two surgical components during a surgical procedure in a vessel.



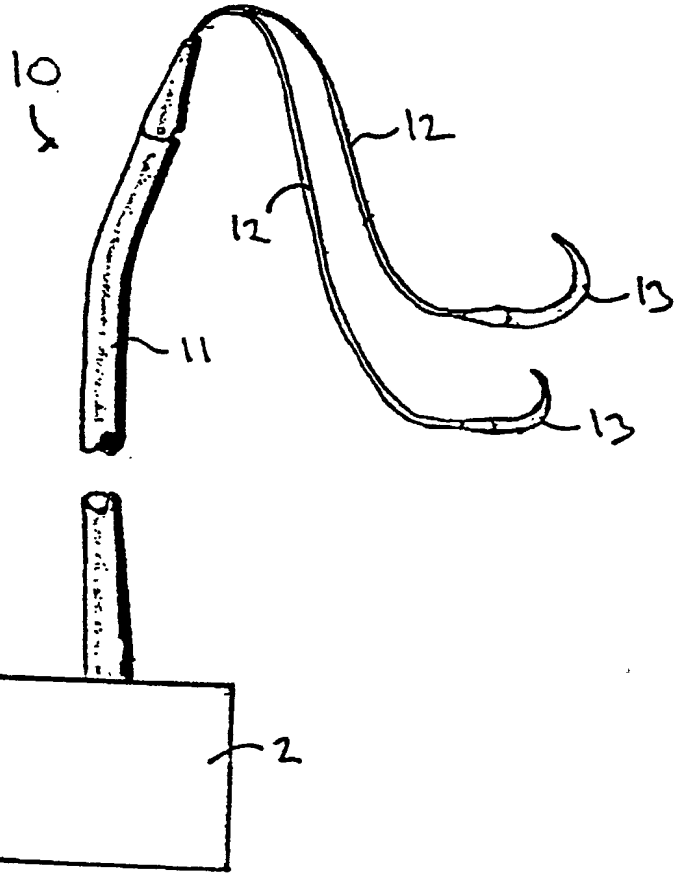


FIG. 1

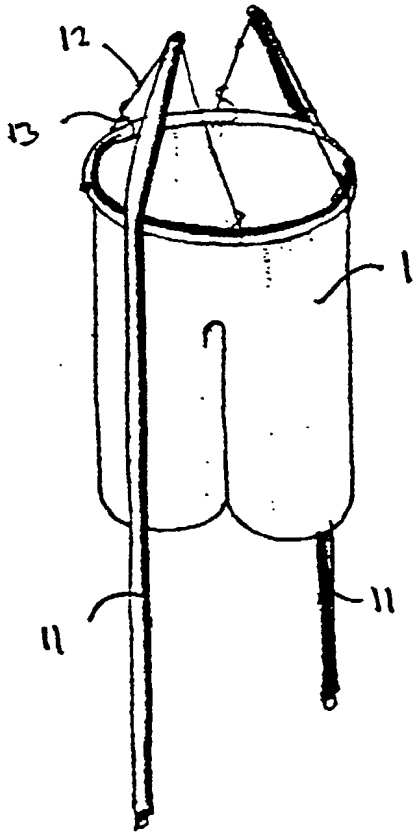


FIG. 2

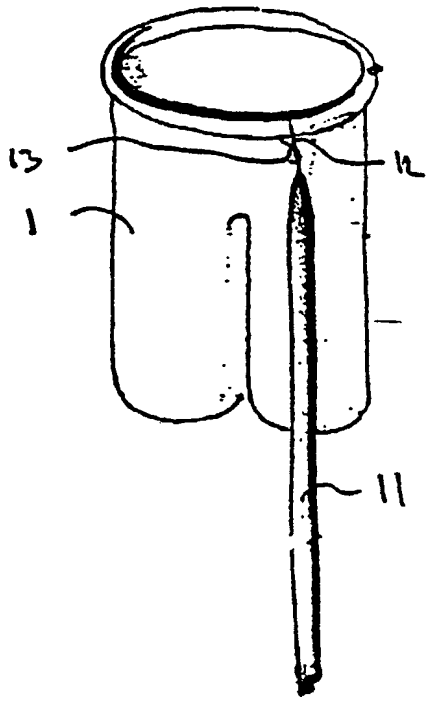


FIG. 3

FIG. 4

FIG. 5

FIG. 6

FIG. 7

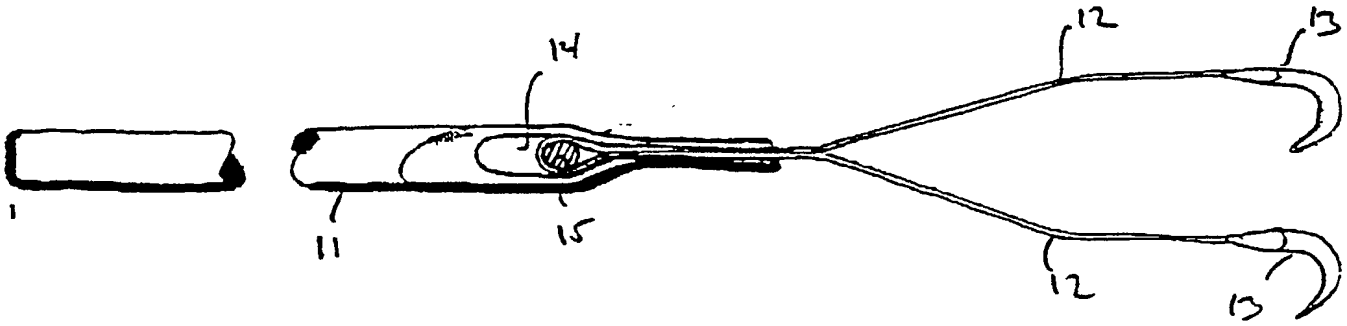


FIG. 8

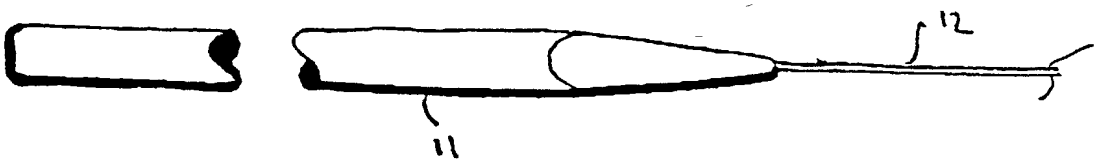


FIG. 9

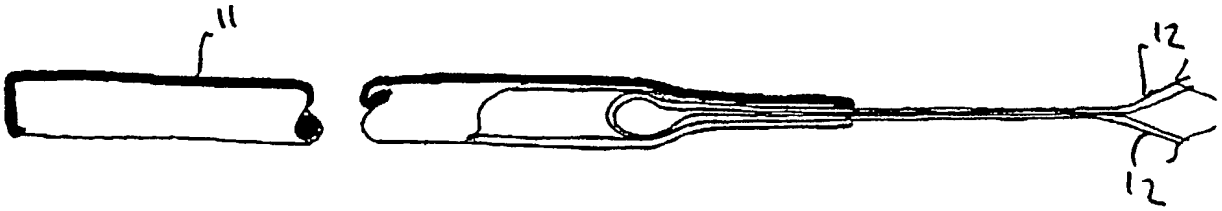


FIG. 10

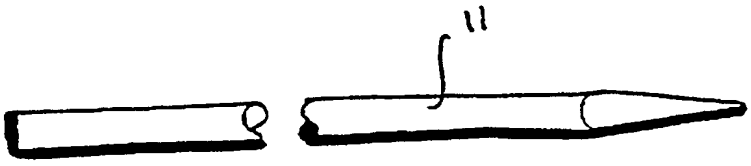


FIG. 11

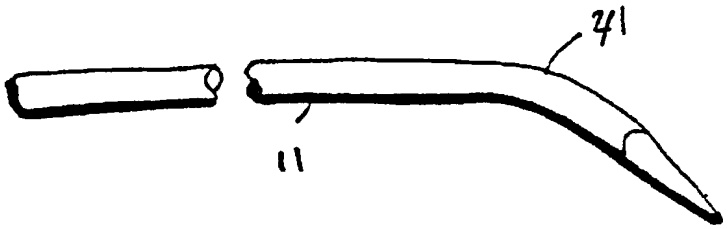


FIG. 12

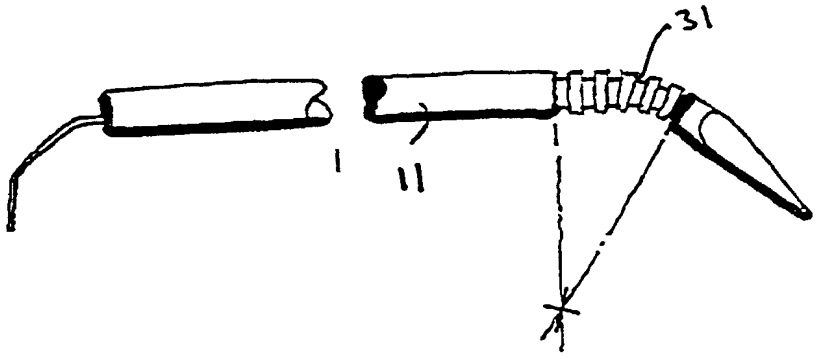


FIG. 13

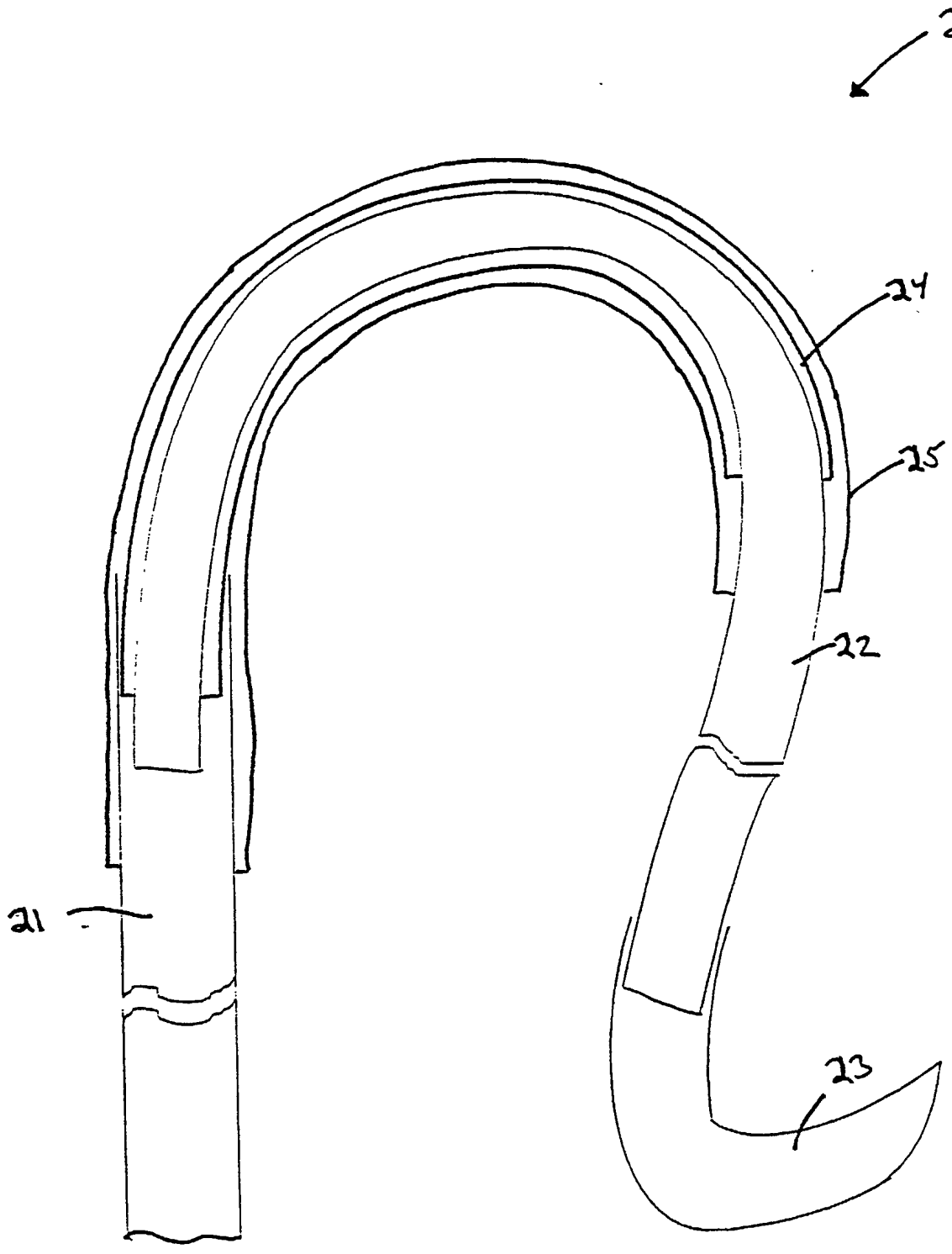


FIG.14

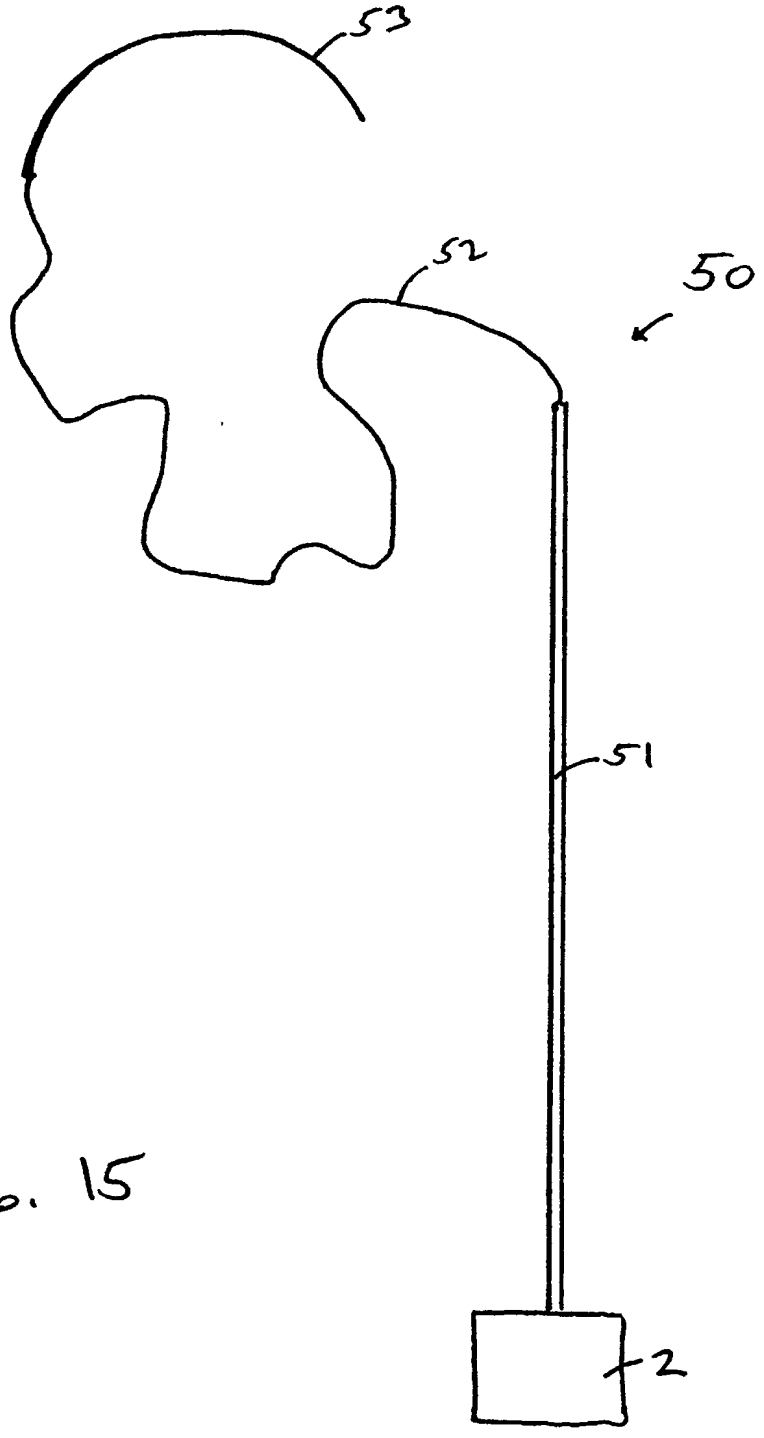


FIG. 15

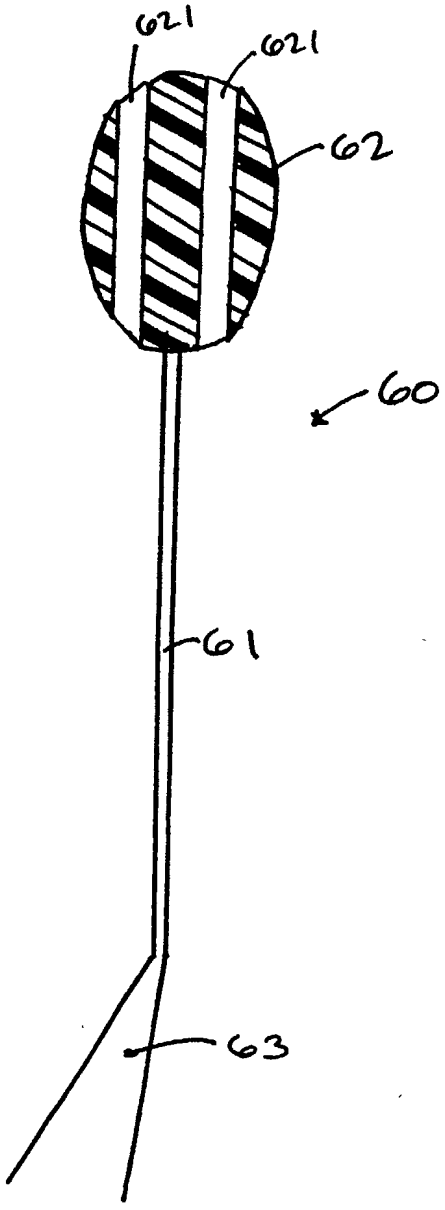


FIG. 16

FIG. 17

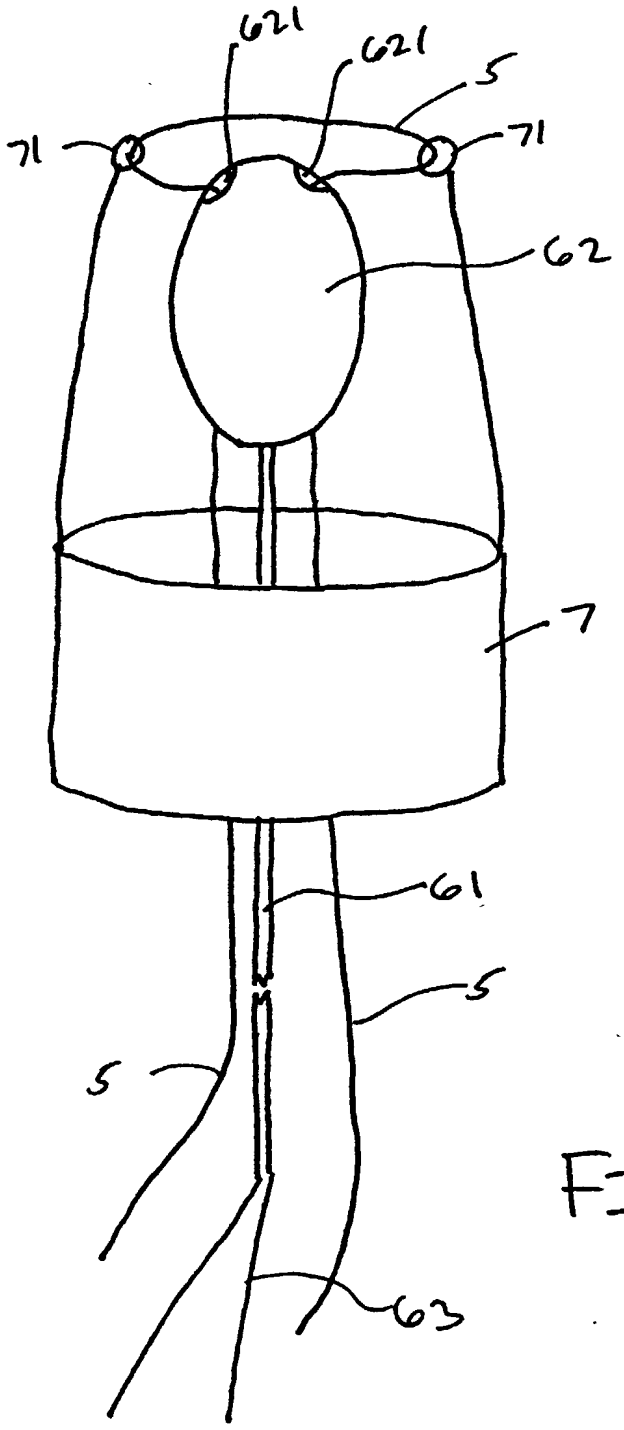


FIG. 18

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

[X] Declaration Submitted with Initial Filing OR [ ] Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	23660-00623
First Named Inventor	Howard M. Tanner, et al.
COMPLETE IF KNOWN	
Application Number	TBA
Filing Date	Herewith
Group Art Unit	TBA
Examiner Name	TBA

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SURGICAL GUIDE LINE ASSEMBLY AND SEPARATOR FOR USE DURING A SURGICAL PROCEDURE

(Title of the Invention)

the specification of which

[X] is attached hereto

OR

[ ] was filed on (MM/DD/YYYY) [ ] as United States Application Number or PCT International Application Number [ ] and was amended on (MM/DD/YYYY) [ ] (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
PCT/US/00/03871		02/04/2000	[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]

[ ] Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR : ☐ A petition has been filed for this unsigned inventor

1-00

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Inventor's Signature [signature] Date 03.26.02

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City	State	ZIP	Country

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname

Inventor's Signature Date

Residence: City	State	Country	Citizenship

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City	State	ZIP	Country

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(Title of the invention)

the specification of which

[X] is attached hereto

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Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	Certified Copy Attached? NO
PCT/US/00/03871		02/04/2000	[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
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NAME OF SOLE OR FIRST INVENTOR : ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname

Inventor's Signature	Date

Residence: City	State	Country	Citizenship

Mailing Address

City	State	ZIP	Country

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

2-00

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☐ Additional inventors are being named on the ___supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.